Errata for the Briefing Document for the Oncologic Drugs Advisory Committee

ODAC Meeting Date: June 20, 2012

NDA: 202714

Company: Onyx Pharmaceuticals

Drug: Carfilzomib (Kyprolis)

Applicant's Proposed Indication: Treatment of patients with relapsed or refractory multiple myeloma who have received at least 2 prior lines of therapy that included a proteasome inhibitor and an immunomodulatory agent

On page 2, paragraph 1, line 1, replace "November" with "September".
On page 4, paragraph 4, lines 2 and 4, replace "full" with "regular"
On page 4, paragraph 4, line 4, before "Both", insert "There is extensive evidence supporting the use of thalidomide in the treatment of patients with multiple myeloma."
On page 4, paragraph 4, line 6, before "All" insert "Steroids are an important treatment for multiple myeloma frequently used in combination with IMiDs and bortezomib. Bortezomib was approved under the accelerated approval pathway, but has since been converted to regular approval."
On page 4, Replace Table 1 in the briefing document with Table 1 below

Table 1. FDA Approved Drugs for Multiple Myeloma

Class	Drug	FDA Approval
Alkylating agents	Melphalan Cyclophosphamide	Regular Regular
Anthracyclines	Liposomal doxorubicin (Doxil™)	Regular
Nitrosureas	Carmustine	Regular
ImiDs	Thalidomide Lenalidomide	Accelerated Restricted Distribution (Subpart H)
Proteasome Inhibitors	Bortezomib	Accelerated converted to Regular

On page 8, last paragraph, line 1, delete "facial edema", "confusion"
On page 11, last paragraph, line 2, delete "percent"
On page 12, last paragraph, line 7, replace "24.2" with "34.2"

On page 19, Table 19, replace Disease Progression “21” with “22”
On page 19, Table 19, replace Multi-Organ Failure “2” with “1”
On page 19, Table 19, replace Sepsis “2” with “1”
On page 19, Table 19, replace Total “38” with “37”
On page 22, Table 23, hepatobiliary disorders last column replace “8 (2)” with “1 (<1)”
On page 23, Replace Table 24 with Table 24 below

Table 24. SAEs for Patients with Multiple Myeloma Enrolled in Study 3 (Shown in Decreasing Order by Organ Class)

Organ Class	N=266 n (%)
Infections and infestations	39 (15)
General disorders and administration site conditions	29 (11)
Cardiac disorders	21 (8)
Respiratory, thoracic and mediastinal disorders	21 (8)
Renal and urinary disorders	15 (6)
Nervous system disorders	14 (5)
Metabolism and nutrition disorders	13 (5)
Musculoskeletal and connective tissue disorders	12 (5)
Blood and lymphatic system disorders	10 (4)
Investigations	8 (3)
Vascular disorders	7 (3)
Gastrointestinal disorders	6 (2)
Psychiatric disorders	4 (2)
Hepatobiliary disorders	2 (1)
Neoplasms benign, malignant and unspecified	2 (1)
Endocrine disorders	1 (<1)
Eye disorders	1 (<1)
Immune system disorders	1 (<1)
Injury, poisoning and procedural complications	1 (<1)

*Patients may be counted in more than 1 organ class.

On page 26, Table 27, last row, Days After Last Dose replace “1” with “2”